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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/627,533
Inventor(s) : Donald Lynn Bissett et al.
Filed : 07/25/2003
Art Unit : 1614
Examiner : Roberts, Lezah
Docket No. : 9332
Confirmation No. : 2912
Customer No. : 27752
Title : Regulation of Mammalian Keratinous Tissue Using N-Acyl
Amino Acid Compositions

DECLARATION OF GARY KELM UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

All statements made herein are true to the best of my knowledge, or, if made upon information and belief, are believed to be true.

I received a BS degree in Chemical Engineering from Rose-Hulman Institute of Technology in 1973, an MS degree in Pharmaceutical Science in 1977 from the University of Cincinnati, and a PhD in Biopharmaceutics in 1991 from the University of Cincinnati. I have been employed by The Procter & Gamble Company of Cincinnati, Ohio since 1973, assignee of the present application, where I am currently employed as a Research Fellow.

I supervised the experiments related in this declaration.

It is my intent in this current declaration to demonstrate that a numerical increase in the *in vitro* transdermal niacinamide skin permeation results when niacinamide is combined with N-acyl amino acid (Sepi-white), in comparison to niacinamide skin permeation when used without the Sepi-white.

An *in vitro* skin permeation test was performed on split-thickness human cadaver skin using radio-labeled niacinamide as a tracer. The test products consisted of a standard oil-in-water emulsion containing 5% niacinamide with and without 1% Sepi-white dissolved in the oil phase. Approximately 5 μ L of each product was applied to cadaver skin in six Franz diffusion cells (0.79 cm²) previously randomized to treatment based upon tritiated water flux. After 24 hr, residual product was removed from the skin by wiping with filter paper, and the amount of radiolabel in the residual product, skin and receptor (phosphate buffered saline with 1% polysorbate 20) determined by liquid scintillation counting. The results from this test are as follows:

Treatments	Percent of Recovered Radiolabel						Total	
	N	Receptor		Total Skin			Permeated	
		Mean	SEM	Mean	SEM		Mean	SEM
O/W Emulsion without Sepi-White	6	32.2	5.0	21.7	3.5		53.9	4.0
O/W Emulsion with Sepi-White	6	36.0	10.7	27.9	5.8		63.9	8.3

Further Declarant sayeth not.

12/7/07

Date

Gary R. Kelm

Gary Kelm

18 U.S.C. §1001 Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or advice a material fact, or makes any false, fictitious or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than \$10,000 or imprisoned not more than five years, or both.